4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1443]

# Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting comment on the draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Elements and Terminologies for the electronic submission of PQ/CMC data. Building on the Agency's previous *Federal Register* notices published on July 11, 2017, and March 18, 2022, requesting comments on PQ/CMC data elements and controlled terminology, the Agency is continuing to seek comment on the accuracy, suitability, and appropriateness of revised and/or new data elements and terminologies for submission of PQ/CMC data. In addition, the progress toward the establishment of standardized pharmaceutical data elements and terminologies will require further interactions between the Agency and interested parties and various stakeholders, including industry. Accordingly, FDA is planning to request comment on additional PQ/CMC data elements and terminologies over time. FDA is establishing an open docket to facilitate efficient receipt of comments and public posting of updated draft documents on PQ/CMC data elements and terminologies.

DATES: Comments may be submitted to this docket at any time.

ADDRESSES: You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. FDA-2023-N-1443 for "Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies; Request for Comments." Received comments filed in a timely manner will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Scott Gordon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993-0002, Gideon.Gordon@fda.hhs.gov, 240-402-8560; Diane Maloney ,

Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Norman Gregory, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., HFV-143, Rockville, MD 20855, Norman.Gregory@fda.hhs.gov, 240-402-0684.

SUPPLEMENTARY INFORMATION:

## I. Background

PQ/CMC is a term used to describe manufacturing and testing data of pharmaceutical products. PQ/CMC encompasses topics such as drug stability, quality specification, batch formula, and batch analysis, which are important aspects of drug development and manufacturing. PQ/CMC plays an integral part in the regulatory review process and life-cycle management of pharmaceutical products. The development of a structured format for PQ/CMC data will enable consistency in the content and format of PQ/CMC data submitted, thus providing a harmonized language for submission content, allowing reviewers to query the data, and, in general, contributing to a more efficient and effective regulatory decision-making process by creating a standardized data dictionary.

The impetus for this standardization effort was the provisions from the 2012 Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), which authorized the Agency to require certain submissions to be submitted in a specified electronic format. PQ/CMC standardization supports FDA's regulatory needs in receiving structured and standardized pharmaceutical quality data and includes two objectives: (1) to standardize the pharmaceutical quality data that is currently received by FDA in electronic common technical document (eCTD) Module 3 (and relevant sections of Module 2) from the sponsoring organizations, and (2) to use these structured elements and develop a Health Level 7 Fast Health Interoperability Resources data exchange solution.

On July 11, 2017, FDA published a *Federal Register* notice requesting comment on a draft PQ/CMC Data Elements and Controlled Terminology document (82 FR 32003). That

document proposed structured data standards for a set of eCTD Module 3 content. Based on a range of public feedback, FDA published a *Federal Register* notice on March 18, 2022 (87 FR 15435), requesting comment on a significantly revised and expanded set of data elements and terminologies, including additional subject areas of Module 3. The information released for public comment is not intended to be comprehensive in covering all eCTD product quality information, only those concepts that were considered amenable to structuring and would bring value to the quality review process. This information should not be viewed as guidance, technical specification, or an implementation guide, as it is meant solely for comment.

Through this notice, the Agency is continuing to seek comment on the accuracy, suitability, and appropriateness of revised and/or new data elements and terminologies for submission of PQ/CMC data. The Agency intends to issue guidance on the standardization of PQ/CMC data elements and terminologies for electronic submissions.

## II. Establishment of a Docket

FDA is establishing an open docket on matters related to PQ/CMC Data Elements and Controlled Terminologies. Coinciding with publication of this notice, a document will be available at FDA's PQ/CMC web page designated as "Chapters," each of which will cover information relevant to selected parts of eCTD Module 3 and/or Module 2.3. The first Chapter, Chapter 1, is provided solely for context as it is a reiteration of content previously released for comment. FDA is not seeking comment on the content of Chapter 1. Chapter 2 in this document is the first new Chapter, which provides draft designs of data elements and terminologies, in some cases new and in other cases updated from Chapter 1, associated with PQ/CMC subject areas and concepts and scoped to some of what is currently submitted in Module 3 of the eCTD submission. Since the data elements and terminologies in Chapter 2 are new and/or updated, review of Chapter 1, solely as a reference, is highly recommended.

After publication of this notice with Chapter 2 of the PQ/CMC Data Elements and Terminologies document, subsequent Chapters will be posted on FDA's PQ/CMC web page

(https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-qualitychemistry-manufacturing-controls-pqcmc). Public comments, specifying to which Chapter the comments are submitted, can be made to the open docket. Comments may be submitted to this docket at any time, but comments should be submitted on new Chapters within 60 days of being posted on FDA's PQ/CMC web page to ensure that the Agency considers your comment before it begins work on the final version of the Chapter. FDA will aim to provide a new Chapter of the PQ/CMC Data Elements and Terminologies periodically. FDA is targeting posting updates to this content to FDA's PQ/CMC web page by the end of the calendar months of March, June, September, and December of each year. This update may consist of a note that there is no new content for review in this period or, alternatively, that there is new content to be reviewed for comment, along with a link to the relevant documentation, background, and instructions on submitting comments.

## III. Electronic Access

Persons with access to the internet may obtain the draft data elements and terminologies at either https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-qualitychemistry-manufacturing-controls-pqcmc or https://www.regulations.gov.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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